



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|--|---------------|-----------------------|------------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/520,745 | 08/22/2005 | Colin Maurice Casimir | 20050022.OR1 | 3261 |
| 23595 | 7590 | 12/04/2008 | EXAMINER | |
| NIKOLAI & MERSEREAU, P.A. 900 SECOND AVENUE SOUTH SUITE 820 MINNEAPOLIS, MN 55402 | | | SHEN, WU CHENG WINSTON | |
| ART UNIT | PAPER NUMBER | | | |
| | | 1632 | | |
| MAIL DATE | DELIVERY MODE | | | |
| 12/04/2008 | PAPER | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|---|--|---|
| Advisory Action Before the Filing of an Appeal Brief | Application No. 10/520,745 | Applicant(s) CASIMIR, COLIN MAURICE |
| | Examiner WU-CHENG Winston SHEN | Art Unit 1632 |

—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED 11 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) The period for reply expires ____ months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

- (a) They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) They raise the issue of new matter (see NOTE below);
- (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. Applicant's reply has overcome the following rejection(s): _____.

6. Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 43-48 and 50-56.

Claim(s) withdrawn from consideration: 49 and 57-67.

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fail to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. Note the attached *Information Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). _____.

13. Other: _____.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632

Continuation of 3. NOTE:

Independent claim 46 is proposed to be amended to recite in step (i) "exogenous nucleic acid", and in step (ii) "expressing the viral nucleic acid and exogenous nucleic acid encoding the passenger peptide binding moiety so that the passenger peptide binding moiety is provided at a cell membrane and a viral particle buds from said packaging cell membrane thereby allowing the passenger peptide binding moiety to be incorporated into the viral particle to modify its first cell binding activity, wherein the passenger peptide binding moiety is selected from the group consisting of cell growth factors, antibodies or antigen-binding fragments thereof, moieties that recognize a target cell - specific surface antigen, and moieties that are at least a part of a member of a binding pair comprising a target -- cell specific cell - surface receptor and its ligand and wherein said passenger peptide is other than one naturally derived from the virus or said packaging cell."

The proposed claim amendments raise new issues that would require further consideration and/or search. For instance, the proposed amendments of claim 43 render the claims more narrow in scope by incorporation of limitations recited in cancelled claim 46 into claim 43 and by alteration of "nucleic acid" to "exogenous exogenous nucleic acid". Additionally, certain embodiments recite that the passenger is one that is other than one "naturally" derived from the virus. These proposed claim amendments would require further consideration in terms of rejections under 35 USC 112, first and second paragraphs, and/or search of prior arts pertaining to "exogenous nucleic acid" in the context of viral packaging cell, as well as consideration of non-naturally derived passenger peptides, for example.

With regard to Applicant's assertion that majority of proteins on the cell surface become incorporated into retroviral particle based on the teachings of Hammarstedt (See page 7 of Applicant's reply filed on 11/11/2008), this issue will require further consideration in light of proposed claim amendments in the context of "exogenous nucleic acid" that expresses passenger peptides, recited in proposed amended claim 43, which is other than "naturally" derived from the virus. Pertaining to this issue, Applicant is reminded that incorporation of a cellular protein into a retroviral coat does not equal to modification of cell binding activity of the viral particle as claimed.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's arguments have failed to overcome the rejection of claims 43-48 and 50-56 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention BECAUSE Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

Applicant's arguments have failed to overcome the scope of enablement rejection of claims 43-48 and 50-56 under 35 U.S.C. 112, first paragraph BECAUSE Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

Applicant's arguments have failed to overcome the rejection of claims 43-46 and 54-56 under 35 U.S.C. 102(b) as being anticipated by Soong et al. (Soong et al., Molecular breeding of viruses. 25(4): 436-9, 2000) BECAUSE Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

Applicant's arguments have failed to overcome the rejection of claims 43, 48, 50 and 51 under 35 U.S.C. 103(a) as being unpatentable over Soong et al. (Soong et al., Molecular breeding of viruses. Nature 25(4): 436-9, 2000) taken with Dropulic et al. (U.S. patent No. 6,114,141, issued Sep. 5, 2000) BECAUSE Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

Applicant's arguments have failed to overcome the rejection of claims 43, 48, 52 and 53 under 35 U.S.C. 103(a) as being unpatentable over Soong et al. (Soong et al., Molecular breeding of viruses. 25(4): 436-9, 2000) taken with Guber et al. (U.S. patent No. 569,177, issued Nov. 25, 1997) BECAUSE Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

Applicant's arguments have failed to overcome the rejection of claims 43 and 47 under 35 U.S.C. 103(a) as being unpatentable over Soong et al. (Soong et al., Molecular breeding of viruses. 25(4): 436-9, 2000) taken with Yajima et al. (Retroviral vector targeting human cells via c-Kit-stem cell factor interaction. Hum Gene Ther. 9(6): 779-87, 1998) BECAUSE Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.